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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,010	06/26/2003	Ed Austin	39262/285776	4956
30559 7590 12/19/2006 CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			EXAMINER SHAFFER, RICHARD R	
			ART UNIT	PAPER NUMBER
			3733	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/19/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/607,010	Applicant(s) AUSTIN ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34, 36 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 6-15, 22, 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16-21, 23-25, 28-34, 36 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/6/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The amendments to the specification filed on November 6th, 2006 are acknowledged and accepted by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 25 now recites "the biasing elements adapted to bias the first and second jaws together toward each other." From applicant's own specification: "Clamp bolts 352 may be urged by biasing elements, such as springs 356, such that first jaw 346 and second jaw 348 tend to push together to stay loosely secured to bone pins prior to tightening clamp bolts 352." The jaws are not the ones being urged together, the springs are maintaining a loose connection between the jaws thereby **biasing them apart not together**.

Claims 28 and 29 are rejected for being dependent upon a non-enabled base claim.

The limitation will hold no weight for examination purposes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 16-19, 21, 23, 30-34, 36 and 41 rejected under 35 U.S.C. 102(b) as being anticipated by Faccioli et al (PCT Publication WO 00/40163).

Faccioli et al disclose an external fixation apparatus comprising: a first member (3) attachable to the tibia (**Figure 2B**) by pins (5); a second member (**2, 20 and 35 together, with 20 including only a single prong**) coupled to the first member through a lockable (at least when the system is fixed) ball joint (top of 2, bottom of 3, **Figure 2B**); a the second member having a first end portion (top of 2) that can be transversely translated along two axes/dimensions relative to a second end portion (bottom of 20) either when not connected or by angling portion 2 relative to portion 20 (thereby being transverse) and telescopically extending the first end away from the second end; a shaft (35) extends transversely from the single prong of (20) and including a groove (that extends at least along a portion of the circumference for receiving a pin 37); an asymmetric pin clamp (40, 50) rotatable about the shaft (35); the pin clamp having first (40) and second (50) jaws; a hole (38) within the first jaw (4) that receives shaft (35); a bolts (43, 59) pass through openings in the first and second jaws to bias/tighten the clamps together; the pin clamp is attachable to a talus or calcaneus; and a carriage

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(41). It is inherent that to decouple the components, locator pins (37) would be pulled out.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 25, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faccioli et al in view of Wagenknecht (US Patent 5,160,335).

Faccioli et al disclose all of the claimed limitations except for the use of biasing elements received within the openings of the two jaws. Wagenknecht teaches (**Column 6, Lines 37-43**) that the use of springs (**Figure 6**) in the openings of jaws facilitate the introduction of pins through a clamp intended to connect bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include springs or an equivalent biasing element in the device of Faccioli et al to facilitate the introduction of bone pins through the clamp.

Claims 4 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faccioli et al in view Lee et al (US Patent 5,405,347).

Faccioli et al disclose all of the claimed limitations except for a stem body with a carriage fitted within operated by keybolts. Lee et al teach (entire disclosure) a device that allows for angular and lateral adjustment of fixator rods in an infinite number of planes and is operable by screws. The benefit cited by Lee et al was that a surgeon

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could perform minor readjustments to fully align bone fragments without disconnecting the device. It would have been obvious to one having ordinary skill in the art to have provided the device of Lee et al between elements (2 and 20 / replacing the ball-and-socket joint found there) to allow for minor adjustments to fully align bone fragments without detaching the device from itself or the bone pins.

Response to Arguments

Applicant's arguments filed November 6th, 2006 have been fully considered but they are not persuasive. Applicant argues that the joints are not lockable in Faccioli et al. This is not found persuasive because the joints are lockable when the device is fixed, is capable of being locked if glued, welded, or in combination with additional components. Applicant does not state how the invention performs the task of locking, therefore only claiming the ability of being locked however the means.

Applicant further argues that pins (37) of Faccioli et al are not "removably coupled." As stated previously, and again stated, the pins are inherently capable of being removed, therefore it reads upon the claimed limitation.

Applicant argues that Wagenknecht teaches pins biasing jaw portions apart and not together as claimed in claim 25. As explained earlier in the 35 U.S.C. 112, 1st paragraph rejection, applicant states, "Clamp bolts 352 may be urged by biasing elements, such as springs 356, such that first jaw 346 and second jaw 348 tend to push together to stay loosely secured to bone pins prior to tightening clamp bolts 352." Clearly, applicant is performing the same exact task of keeping a "loose" connection to "facilitate" introduction of the bolts and not biasing the jaws together.

Additional arguments are moot in view of the slightly modified interpretation applied in the current office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
December 11th, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER